

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Takruri

Appl. No. : 10,698,320

Filed: October 31, 2003

For : PIRENZEPINE OPHTHALMIC

GEL

Examiner : Fay, Zohreh A.

Group Art Unit : 1618

37 CFR 1.131 DECLARATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

I, the undersigned, do declare and say that:

- 1. I am the inventor of the above-identified application.
- 2. This declaration is to establish completion of the invention of this application in the United States at a date prior to April 29, 2001, the date that appears on Karageozian et al. 2001 Invest. Ophthalmol. Vis. Sci., Vol. 42:S59 (Abstr, No. 330), attached.
- 3. To establish the date of completion of the invention of this application, the attached true copies are submitted as evidence: Exhibit A, Formulation Record, and Exhibit B, Notebook Reference, both exhibits dated prior to April 29, 2001, the dates of which have been removed.

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4. From Exhibit A, Formulation Record, it can be seen that pirenzepine was formulated with hydroxypropyl methylcellulose (HPMC) to form pirenzepine ophthalmic gel. Formulation Record refers to Notebook Reference: 001-096.

- 5. Exhibit B, Notebook Reference 001-96, confirms that hydroxypropyl methylcellulose (HPMC) was formulated with pirenzepine to form pirenzepine ophthalmic gel.
- 6. Acts towards completion of the invention occurred in the state of California, thus in the United States.

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I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or patent issuing therefrom.

Respectfully submitted,

Dated: October 14,2005

By:

Harun Takrur